

**510(K) SUMMARY****PRODUCT CLASSIFICATION NAME:**

Focus  
System, x-ray, extraoral source, / EHD  
Regulation number: 872.1800

**OCT 09 2002****MANUFACTURER:**

Instrumentarium Corp. Imaging Division  
P.O.Box 20 (Street Address: Nahkelantie 160)  
FIN-04301 Tuusula, Finland  
Phone: +358-10-394 6500  
Fax: +358-10-394 6501

Contact person: Kaija Jokela

**UNITED STATES SALES REPRESENTATIVE (US DESIGNATED AGENT):**

Instrumentarium Imaging Inc.  
300 West Edgerton Avenue  
Milwaukee, Wisconsin 53207

Phone: 414-747-1030  
Fax: 414-481-8665

Contact person: Mark Mason

**INTENDED USE:**

Focus is intended to be used for producing diagnostic x-ray radiographs of dentition, jaws and other oral structures.

Instrumentarium Imaging

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<http://www.instrumentarium.com/imaging>

Instrumentarium Corporation • FIN-00031 INSTRUMENTARIUM • Trade Reg. No.12.570 • VAT FI01092226

29 July 2002

**DESCRIPTION:**

The FOCUS is a microprocessor controlled intra-oral x-ray unit with a Load Matching Frequency (LMF) DC generator, which produces dental images on digital and film media. For the digital images the FOCUS is connected to the Sigma USB terminal which is connected to a PC, which reads the image data from a sensor and displays the image on the PC monitor. In order to make installation and service faster and easier the electronics is integrated into the horizontal arm.

**SUBSTANTIAL EQUIVALENCE:**

We consider this product is similar in design, composition and function to the following device introduced into commercial distribution after May 28, 1976:

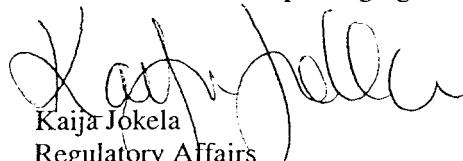
Focus K001729

The technological characteristics of Focus are essentially equivalent to the technological characteristics of predicate device; the only difference is the AEC option, which can be used with Sigma sensor (manufactured by Instrumentarium Imaging, #K001828). The intended uses of the devices are equivalent.

**PERFORMANCE DATA:**

Verification and validation testing was successfully performed to confirm that the modified Focus functions as intended. It was also shown that modified Focus is able to provide images of equivalent diagnostic capability to that of predicate device. Modified Focus is as safe and effective as the predicate device.

Instrumentarium Corp. Imaging Division



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Regulatory Affairs

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## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 09 2002

Instrumentarium Corp.  
Imaging Division  
Attn: Mr. Mark Mason  
Instrumentarium Imaging, Inc.  
300 West Edgerton Avenue  
MILWAUKEE WI 53207

Re: K022630  
Trade/Device Name: Focus with AEC option  
Regulation Number: 21 CFR 872.1800  
Regulation Name: Extraoral source x-ray system  
Regulatory Class: II  
Product Code: 90 EHD  
Dated: July 29, 2002  
Received: August 7, 2002

Dear Mr. Mason:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

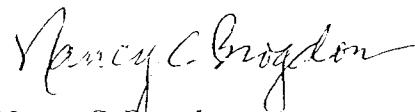
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

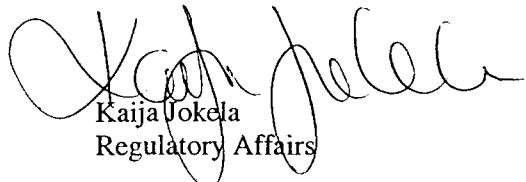
Enclosure

510(k) Number (if known): K022630

Device Name: Focus

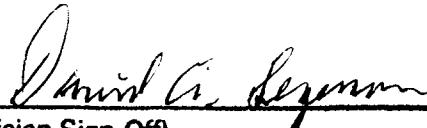
Indications for Use: Focus is intended to be used for producing diagnostic x-ray radiographs of dentition, jaws and other oral structures.

Instrumentarium Corp. Imaging Division

  
Kaija Jokela  
Regulatory Affairs

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
David A. Leyman  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K022630

(Optional Format 3-10-98)